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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,473	12/17/2003	Donald K. Jones	CRD5061	8194

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
AHMED, AAMER S	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/738,473	JONES ET AL.	
	Examiner	Art Unit	
	Aamer S. Ahmed	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Receipt of amended claims 21, 24 and 23 are acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 5,14 are 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Currie et al ('454). Currie describes a support member; a bioactive agent disposed on the support member; and an outer barrier coating disposed on the bioactive agent, the outer barrier coating being non-water soluble but dissolving when an external agent is applied to the outer coating and exposing the bioactive agent when in the presence of a biological agent. Moreover Currie describes that the bioactive agent takes the form of a coating applied to the support member and is integral with the support member. (See Figure 3 and Columns 8 and 9).

Thus Currie reasonably appears to teach and disclose every element of claims 1, 4, 5, 14 and 19.

Claims 26-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosenbluth et al U.S. Patent Number 6,015,424. Rosenbluth et al discloses a method of treating aneurysm (see abstract) comprising the steps of providing a vascular occlusive device comprising a support member, (54) a bioactive agent (col. 3 line 6) disposed on the support member (54), and a barrier exhibiting (60) the characteristic of normally preventing a reaction between the bioactive agent and a bodily fluid and of exposing a portion of the bioactive agent when an external agent (col. 9 line 37) is applied to the barrier; inserting a delivery catheter into a blood vessel (see abstract) through the blood vessel until the distal tip is adjacent an aneurysm within the blood vessel; delivering the vascular occlusive device with the delivery catheter into an aneurysm; and applying the external agent through the catheter and into the aneurysm to thereby cause a reaction between the bioactive agent and the bodily tissue (col. 4 line 18).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 3, 6,7,10-13, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Currie et al ('454) in view of Eder ('550). Currie describes an implantable medical device comprising a support member, a bioactive agent disposed on said support member; and, an outer barrier disposed on said bioactive agent to prevent exposure of said bioactive agent to bodily fluid when said vascular occlusive device is inserted into a blood vessel, said outer barrier exhibiting the characteristic of being substantially inert to bodily but dissolving when exposed to an external agent. (See Figure 3 and Columns 8 and 9).

Currie fails to disclose, that the support member is a vascular embolic device taking the form of a helically wound metallic coil, that the bioactive agent is comprised of a synthetic polypeptide, that the bioactive agent takes the form of a thrombus inducing coating.

As to Claims 2 and 20 Eder discloses a vascular occlusive device wherein the support member is a vascular occlusive embolic coil. (See Figure 1).

As to Claim 3, Eder teaches that the support member takes the form of a helically wound metallic coil. (See Figure 1).

As to Claim 6 and 7 Eder teaches that the outer barrier takes the form of a coating applied to the bioactive agent. (See Figure 2).

As to Claim 10, 11, 12 and 13, Eder teaches that the bioactive agent takes the form of a thrombus inducing coating. (See Column 4).

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the implanted device of Currie by adding the structural coil

components and as taught by Eder in order to obtain a more controllable vascular occlusive device.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Currie et al ('454) and Eder ('550) in view of Abrams et al (US2002/0058640). Neither Currie nor Eder discloses that the bioactive material is comprised of polyglycolic acid (See Paragraph 24), and the composition of the outer barrier as comprising of ethylene vinyl alcohol, (See Paragraph 8).

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the implanted device of Currie as modified by Eder by comprising the bioactive material of polyglycolic acid and an outside layer of ethylene vinyl alcohol as taught by Abrams, in order to achieve a more bioactive vascular occlusive device

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Currie et al ('454) and Eder ('550) in view of Wallace ('269). Neither Currie nor Eder discloses that the external agent is comprised of dimethyl sulfoxide.

Wallace et al ('269) does teach that the external agent can be dimethyl sulfoxide. (See Column 4)

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the implanted device of Currie as modified by Eder by adding activation be an external agent of dimethyl sulfoxide, as taught by Wallace in order to obtain a more controllable vascular occlusive device.

Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard et al ('429) in view of Engelson ('754). Sheppard describes a support member, a bioactive agent

disposed on said support member and an outer barrier coating disposed on said bioactive agent, said outer barrier coating exhibiting the characteristic of being non-water soluble but dissolvable when an external activating agent is applied to said outer barrier and wherein the bioactive agent takes the form of a coating applied to the support member and is integral with support member. (See Column 5).

Sheppard fails to disclose neither that the support member is a vascular occlusive embolic coil nor that the bioactive agent takes the form of a thrombus inducing coating.

Engelson does disclose a support member that is a vascular occlusive embolic coil and that the bioactive agent takes the form of a thrombus inducing coating. (See Figure 6 and Column 7).

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the device of Sheppard by adding a support member that is a vascular occlusive embolic coil and that the bioactive agent takes the form of a thrombus inducing coating as taught by Engelson, in order to obtain a more controllable vascular occlusive device.

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard et al ('429) in view of Wallace et al ('914). Sheppard describes a support member, a bioactive agent disposed on said support member, and a barrier exhibiting the characteristic of normally preventing a reaction between the bioactive agent and a bodily fluid and of exposing a portion of said bioactive agent when an external agent is applied to the barrier. Sheppard fails to disclose a method of inserting a delivery catheter into a blood vessel; advancing the distal tip of the delivery catheter through the blood vessel until the distal tip is adjacent an aneurysm

within the blood vessel; delivering said vascular occlusive device with the delivery catheter into an aneurysm.

Wallace does teach a method of inserting a delivery catheter into a blood vessel; advancing the distal tip of the delivery catheter through the blood vessel until the distal tip is adjacent an aneurysm within the blood vessel; delivering said vascular occlusive device with the delivery catheter into an aneurysm; (See Columns 8 and 9).

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the device of Sheppard by adding the method of delivery as taught by Wallace in order to obtain a more controllable vascular occlusive device.

Claims 1-7, 10-25 are rejected under 5 U.S.C. 103(a) as being unpatentable over Hamm et al WO 03/092791 in view of Rosenbluth et al U.S. Patent Number 6,015,424. Hamm et al disclose a vascular occlusive device (20) comprising a support member (25); a bioactive agent (45) disposed on the support member (25); and an outer barrier comprising an activatable agent (60), the outer barrier covering the bioactive agent and exhibiting the characteristics of substantially preventing a reaction between the bioactive agent and body fluid when the vascular occlusive device in inserted into a blood vessel and exhibiting the characteristic of being substantially inert to bodily fluid (page 14 line 14) but dissolving when exposed to an external agent and permitting a reaction between the bioactive agent and bodily fluid upon activation by an external non-electrical activating agent (page 4 line 20). Hamm et al fails to disclose that the activating source is an external fluid nor that the vascular occlusive embolic coil or that the coating is thrombus inducing. Rosenbluth et al teaches a similar device comprising a vascular

occlusive embolic coil (see abstract) taking the form of a helically wound metallic coil with a thrombus inducing bioactive agent and is integral with the support member (col. 3 line 6) and an activatable agent, activatable by an external fluid source (col. 9 line 37). It would have been obvious to a person having ordinary skill in the art at the time of invention by applicant to modify the device of Hamm et al by incorporating the coatings on an embolic coil with an external fluidic activating agent as taught by Rosenbluth in order to control the location of the embolic device (col. 4 line 40).

Response to Arguments

Applicant's arguments filed September 16 2005 have been fully considered but they are not persuasive. Applicant argues that the barrier coating of Currie et al ruptures rather than dissolves, however a portion of the barrier is melted by the external source and undergoes a form of dissolution. Furthermore applicant's argument that the barrier of Currie et al does not exhibit the characteristic of being substantially inert to bodily fluid is not persuasive as the outer barrier is disclosed to be biocompatible (col. 6 line 66). Moreover applicant's argument that it would not have been obvious to combine the microchip device of Sheppard with the embolic coil of Engleson, however it would have been obvious to combine the two reference to better control the delivery of the coils. ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Ahmed

NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700